

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 10 milligrams of dextro-amphetamine sulfate per tablet.

Misbranding, Section 502 (a), the label statement "Each Tablet contains Dextro-Amphetamine Sulfate 10 mg." was false and misleading as applied to a product containing less than the declared amount of dextro-amphetamine sulfate per tablet.

DISPOSITION: May 13, 1954. Default decree of condemnation. The court ordered that the product be delivered to a charitable institution.

4370. Adulteration of suprarenin tablets and procaine hydrochloride and epinephrine tablets. U. S. v. 12,473 Boxes, etc. (F. D. C. No. 36450. Sample Nos. 52638-L, 52639-L, 52641-L.)

LIBEL FILED: March 16, 1954, District of New Jersey.

ALLEGED SHIPMENT: During 1946, from various places outside the State of New Jersey.

PRODUCT: 12,473 boxes, each containing 5 vials, of *suprarenin tablets*, and 20,000 boxes, each containing 5 vials, and 6,300 boxes, each containing 10 vials, of *procaine hydrochloride and epinephrine tablets*, at Jersey City, N. J.

Analysis disclosed that the *suprarenin tablets* contained approximately 57.8 percent of the declared amount of epinephrine, and that the 20,000-box lot and the 6,300-box lot of the *procaine hydrochloride and epinephrine tablets* contained 75 percent and 52 percent, respectively, of the declared amount of epinephrine.

LABEL, IN PART: (Vial) "0.001 Gm. 20 Tablets * * * Suprarenin * * * Brand of Epinephrine (Synthetic) Each tablet contains Suprarenin Bitartrate 0.00182 Gm. equivalent to Suprarenin 0.001 Gm. (1/65 grain)," "20 Soluble Hypodermic Tablets Procaine Hydrochloride And Epinephrine Procaine Hydrochloride, 0.02 Gm.; Epinephrine 0.00005 Gm.," and "20 Tablets #20 Procaine HCl (USP) 1/3 Grain (0.02 Gm.) Epinephrine 1/1200 Grain (0.00005 Gm.)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strengths of the articles differed from that which they purported and were represented to possess since the article in the 12,473-box lot contained less than 0.001 gram (1/65 grain) of epinephrine per tablet; the article in the 20,000-box lot contained less than 0.00005 gram of epinephrine per tablet; and the article in the 6,300-box lot contained less than 1/1200 grain (0.00005 gram) of epinephrine per tablet. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: April 27, 1954. Default decree of condemnation and destruction.

4371. Adulteration of Special Formula ampuls. U. S. v. 1,141 Ampuls * * *. (F. D. C. No. 36226. Sample No. 82548-L.)

LIBEL FILED: January 4, 1954, Western District of New York.

ALLEGED SHIPMENT: On or about November 20, 1953, by the Vitamix Corp., from Philadelphia, Pa.

PRODUCT: 1,141 *Special Formula ampuls* at Rochester, N. Y.

LABEL, IN PART: "5 cc. Amps. Special Formula Each 5 cc. contains: Iron Cacodylate 0.03 gm. Emetine HCl 0.06 gm. In physiological salt solution * * * For Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since the article was represented as a drug suitable for intravenous use and it was not suitable for such use in that it was contaminated with viable micro-organisms and pyrogens.

DISPOSITION: February 12, 1954. Default decree of condemnation and destruction.

4372. Adulteration and misbranding of liver-folic acid-B₁₂ and Foliver. U. S. v. 30 Vials, etc. (F. D. C. No. 36397. Sample Nos. 58616-L, 58617-L.)

LABEL FILED: February 18, 1954, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about October 2 and 7, 1953, from Philadelphia, Pa.

PRODUCT: 30 vials of *liver-folic acid-B₁₂* and 41 vials of *Foliver* at Detroit, Mich. Analyses showed that the products contained less than 50 percent of the declared amount of vitamin B₁₂.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they purported and were represented to possess, namely, 60 micrograms of vitamin B₁₂ per cubic centimeter.

Misbranding, Section 502 (a), the statement "Each cc. contains: Vit. B₁₂ * * * 60 Mcg." appearing on the labels of the articles was false and misleading as applied to the articles, which contained less than 60 micrograms of vitamin B₁₂ per cubic centimeter.

The articles were adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 16, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4373. Misbranding of C-Tone. U. S. v. 87 Bottles, etc. (F. D. C. No. 36158. Sample No. 26489-L.)

LABEL FILED: December 3, 1953, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 22 and 30 and November 4, 1953, by Balanced Foods, Inc., from New York, N. Y.

PRODUCT: 87 8-ounce bottles of *C-Tone* at Philadelphia, Pa., together with a number of circulars entitled "Which of These Dread Killers Threaten Your Advancing Years?"

LABEL, IN PART: (Bottle) "Rich In Activated Enzymes C-Tone The Natural Vitamin C Tonic A splendid aid in quickly correcting conditions caused by deficiency of Vitamin C in the diet. This natural concentrate also supplies other essential nutritional factors as well as generous amounts of Pectin. Four tablespoons furnish: Natural Vitamin C 250 mg. Natural Rutin (Vitamin P Complex) 5 mg. Natural Vitamin K 1 mg. Natural Niacin 0.08 mg. Natural Pectin (Protopectins incl.) 500 mg. Natural Citric Acid 57 mg. Natural Chlorophyll 0.01 mg. and small amounts of natural Vitamin B₁ and B₂. Calcium and Phosphorus in a vegetable extract base rich in activated enzymes. * * * Sale and Exclusive Distributors Byrne Products, Inc. New York 7, N. Y."

*See also Nos. 4369, 4372.